

**REMARKS**

**Formal Matters**

Claims 51-60 and 64-70 remain in this application. Claims 61-63 have been canceled as duplicative.

With respect to cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any objection and/or rejection made by the Office. Applicants expressly reserve the right to pursue prosecution of any subject matter not presently claimed in one or more future or pending continuation and/or divisional applications.

**Claim Objection Under 37 CFR 1.75**

In the Action of Jan. 13, 2005, the Examiner states that claims 61-63 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 55-57.

Without acquiescing to any loss of subject matter, Applicants hereby cancel pending claims 61-63.

**Rejection Under 35 U.S.C. § 112, Second Paragraph**

In the Action of Jan. 13, 2005, the Examiner rejected pending claims 51-70 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse.

In discussing examination under 35 U.S.C. § 112, second paragraph, the MPEP at section 2171 states that "examination is to determine whether or not the claims are precise, clear, correct, and unambiguous." The MPEP at section 2173.02 goes on to state: "compliance with the requirement for definiteness... is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available." The MPEP points out that the Examiner should allow claims which define the patentable subject matter with a "reasonable degree" of particularity and distinctness, and that some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire.

(A) The Examiner alleges that in claim 51, it is unclear where the specific metes and bounds of the phrase "fragment thereof" is in reference to the chimeric, humanized and human antibody.

Applicants submit that these claims meet the threshold requirements of clarity and precision as discussed above.

The pending claim 51 reads:

A method of treating cancer in a mammal, comprising administering an effective amount of hepatocyte growth factor (HGF) receptor antagonist to the mammal, wherein said HGF receptor antagonist comprises a chimeric antibody, humanized antibody, human antibody, or fragment thereof. (emphasis added)

Applicant asserts that, in the context of the whole claim, the specific metes and bounds of the phrase “fragment thereof” are precise, clear, correct, and unambiguous, as said phrase is recited in relation to the phrase “a hepatocyte growth factor (HGF) receptor antagonist”. Therefore, the claim as written meets the 35 USC Section 112, second paragraph requirement of being “precise, clear, correct, and unambiguous.” Claim 51 and dependant claims 52-70 all meet the threshold for clarity and precision, and the claims are compliant with the requirements for definiteness.

(B) The Examiner contends that it is unclear how claim 58 further limits claim 51, apparently because claim 58 recites “said HGF receptor is the c-met receptor”, and apparently because “the HGF receptor is synonymous with the c-met.” Office Action, page 2. The Examiner also alleges that “the recitation of receptor relative to c-met in claim 58 and claim 59 is redundant.” Office Action, page 3 Applicants disagree with the Examiner’s position. In the context of the instant specification (see for example page 7 lines 14-23, discussing HGF receptor and c-met), the teaching of the prior art, as well as the understanding of one skilled in the pertinent art, these phrases, as used in the claims, meet the legal threshold for definiteness because the claims are “precise, clear, correct, and unambiguous.” Indeed, the specification at, for example, page 4, lines 12-13, uses relevant language in a clear and definite manner consistent with the art, for instance using the phrase, “HGF and its c-met receptor” (emphasis added), while citing art in the field that uses this language in a manner that is consistent with the specification and the claims. For example, one of the references cited in the specification bears the title “Hepatocyte Growth Factor-Scatter Factor (HGF-SC) and the C-MET Receptor” (emphasis added.) Therefore, Applicant submits that claims 58 and 59 meet the threshold for clarity and precision, and that the claims are compliant with the requirements for definiteness.

(C) The Examiner states that “binding ability” of claims 67 and 68 is vague and indefinite

because it is unclear if binding ability refers to simply the ability to bind its target, or whether binding ability is intended to quantify the strength of the antibody interaction with the receptor, such as that quantitated as antibody affinity. Applicants submit that there is no vagueness or indefiniteness here as the plain meaning of these words is understood by one skilled in the pertinent art: "binding ability" means simply the ability to bind its target. Indeed, the Examiner's alternative meaning introduces an unnecessary limitation into the claims. Applicant respectfully submits that claims 67 and 68 meet the threshold of clarity and precision for compliance with the requirement for definiteness.

In view of above, withdrawal of the instant rejection is respectfully requested.

Judicially Created Double Patenting Rejection

Claims 51-54, 58-60, 64-66, 69 and 70 are rejected for obviousness-type double patenting as allegedly being unpatentable over claims 1-11, 15 and 16 of U.S. Pat. No. 6,214,344. Claims 51-56, 58-62, 64-70 are rejected for obviousness-type double patenting as allegedly being unpatentable over claims 1-11, 15 and 16 of U.S. Pat. No. 6,214,344 in view of Scholm, 1991. Claims 57 and 63 are rejected for obviousness-type double patenting as allegedly being unpatentable over claims 1-11, 15 and 16 of U.S. Pat. No. 6,214,344 in view of Schlom 1991 and the abstract of Marks 1991. Claims 51-56, 58-62, 64-70 are rejected for obviousness-type double patenting as allegedly being unpatentable over claims 1-5, and 11-19 of U.S. Pat. No. 6,207,152. Claims 51-70 are rejected for obviousness-type double patenting as allegedly being unpatentable over claims of U.S. Pat. No. 6,207,152 in view of Schlom 1991 and the abstract of Marks 1991.

Without acquiescing to the instant rejection, and without acceptance of the Examiner's characterizations of claims and of the art, Applicants will execute a terminal disclaimer upon an indication of allowable subject matter in order to expedite allowance of the instant case.

Solely for discussion purposes, Applicants note that some of the Examiner's comments in the Office Action of January 13, 2005 are believed to contain inaccuracies. For example, Office Action page 4: (i) the Examiner contends that claim 8 of the '344 patent refers to "a FAB fragment" – *claim 8 of '344 does not recite this term*; (ii) the Examiner refers to Claim 70 of the '344 patent which the Examiner asserts would specify "that the antibody is produced by the hybridoma of ATCC-HB-11894" – *there is no issued claim 70 in patent '344*. Additionally see, for example, Office action Page 7: (iii) Applicants

disagree with the Examiner's generalization between the term "carcinoma" in instant claims 52 and 53 and the terms "breast", "pancreatic", "colon", and "lung" cancer in claims 2-5 of patent '152, respectively. The Examiner has not provided a scientific or clinical basis for equating the two sets of terms as alleged in the Office Action. (iv) On page 7 of the Office Action, second half of first paragraph, the Examiner refers to claim 1 of the instant case. Applicants note that claim 1 of the instant case is not currently pending. (v) Applicants additionally wish to point out that the specific language of claims 15 and 17 of the '152 patent is "identifying biological characteristics." (Emphasis added.) The term "biological" was missing in the Examiner's recitation of these claims.

SUMMARY

Claims 51-60 and 64-70 are pending in the application. Claims 1-50, and 61-63 are canceled without prejudice to later prosecution.

If in the opinion of the Examiner, a **telephone conference** would expedite the prosecution of the subject application, the Examiner is **strongly encouraged** to call the undersigned at the number indicated below.

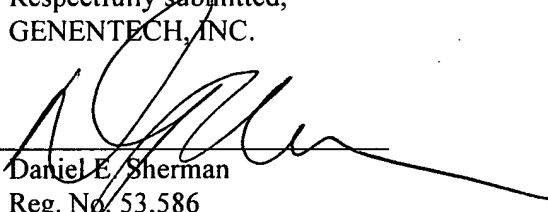
This response/amendment is submitted with a transmittal letter and petition for a one-month extension of time and fees. In the unlikely event that this document is separated from the transmittal letter or if fees are required, applicants petition the Commissioner to authorize charging our Deposit Account 07-0630 for any fees required or credits due and any extensions of time necessary to maintain the pendency of this application.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,  
GENENTECH, INC.

Date: May 13, 2005

By: \_\_\_\_\_

  
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